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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,377	05/03/2001	Gregory Prince	469201-540	8081

7590 06/16/2006

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/848,377

Applicant(s)

PRINCE ET AL.

Examiner

Myron G. Hill

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,25-27 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/20/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/20/2006 has been entered.

This action is on claims 31-40.

### ***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed 3/20/2006 is enclosed.

### ***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Rejections Necessitated By Amendment***

***Claim Rejections - 35 USC § 103***

Claims 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince *et al.* (US PAT 5290540, 1 March 1994 issue date) and Johnson *et al.* (USPAT 5824307, October 20, 1998 issue date) in view of Bulow *et al.* and Smyth *et al.*

The claims are drawn to a method of treating RSV with a combination treatment of antiviral antibody and anti-inflammatory agent.

Applicant argues that the references alone or in combination do not teach systemic administration of both antiviral and anti-inflammatory agents. Applicant also argues that Prince *et al.* (NPL post filing) teach the reluctance of using systemic steroids and Bulow *et al.* (latest IDS) teach against the use of steroids systemically.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Bulow *et al.* does not teach away from the combination therapy with antibodies. Bulow *et al.* teach that steroids were not effective as an adjunct to conventional RSV therapies (page 3, column 2, top). Also, the teachings do not indicate that there was an adverse effect, but that the use of the steroid did not result in an improvement of the conventional therapy outcome.

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Prince *et al.* (NPL post filing) teach systemic combination administration and the reluctance to use systemic steroid (conclusion). This reluctance is as discussed above in Bulow *et al.*, that there was not a positive outcome to the treatment.

Prince *et al.* (US PAT) was discussed in the previous action and teach anti-viral antibody and anti-inflammatory agent combination treatment of RSV infection.

Prince *et al.* do not teach systemic administration of anti-infectious agent antibody (MEDI-493) or steroid.

Johnson *et al.* was discussed in the previous action.

One of ordinary skill in the art at the time of invention would have known that antibodies could be administered systemically with the expectation of success (column 1, lines 33-35 of Johnson *et al.*). The use specific recombinant antibodies avoids the limitations as taught in Johnson *et al.* that RSVIG therapy has the disadvantages of large volumes and venous access, and regular hospital visits (column 1, lines 37-48). The use of the antibodies of Johnson *et al.* avoids the limitations by being higher titer (antiRSV and antibodies per ml) and thus requires less antibody to be delivered and because it is a humanized recombinant antibody, it would not raise an inappropriate immune response to the antibody itself.

The use of systemic administration of steroids was known and was not known to be detrimental to the patient (Bulow *et al.*)

Prince *et al.* (US PAT) teach that the combination of antiviral and anti-inflammatory are useful in treating respiratory infections because the combination act on the virus and the patient (column 4, lines 60-65). RSV is known in the art to produce an

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inflammatory response (conclusion of abstract, Smyth *et al.*). One of skill in the art at the time of invention would be motivated to use a combination therapy to treat RSV infection because the combination treats both the virus and the body's response to the virus.

Thus, it would be *prima face* obvious to modify the method of Prince *et al.* to use the antibody of Johnson *et al.* and give the antibody systemically and anti-inflammatory agent systemically with the expectation of success because Prince *et al.* (US PAT) has shown that the anti-inflammatory is used against inflammatory response and is not used as an antiviral.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill  
Patent Examiner  
6 June 2006

*mt* 6/11/06



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